

**EPA Reg. No. 81598-12**  
**Vol. 2**

# PROCESSING REQUEST

Reg # 81598-12

Decision # S13501

Description: New Basic, A14#1 & A14#2

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

☐ Dated:

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent** (see jacket):

☒ New CSF(s) Dated: Basic, A14#1 & A14#2 01/25/2016

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Shanta Adeeb

Division: RD/HB

Phone: 347-0502

Date: 3/3/ 2016



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

March 3, 2016

James M. Wagner  
Agent Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 9707

Subject: Condition of Registration – Impurities of Toxicological Concern  
Product Name: Rotam Dicamba Technical  
EPA Registration Number: 81598-12  
Application Date: January 25, 2016  
Decision Number: 513501

Dear Mr. Wagner:

The Agency has reviewed the study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study has been classified as acceptable. The condition of registration is considered fulfilled.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 01/25/2016
- Alt #1 dated 01/25/2016
- Alt #2 dated 01/25/2016
- Alt #3 dated 01/19/2015

If you have any questions, please contact Shanta Adeeb by phone at 703-347-0502, or via email at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Kathryn V. Montague".

Kathryn Montague, Product Manager 23  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure

**FEE**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**DOCUMENT CONTAINS CONFIDENTIAL INFORMATION**

DP BARCODE: 431648; DECISION NO.: 513501; Reg. No. No.:81598-12

PRODUCT NAME: Rotam Dicamba Technical: PC CODE(s): 029801;

DATE: February 28, 2016

SUBJECT: Product Chemistry Review of Rotam Dicamba Technical

FROM: Akiva Abramovitch, Ph.D.  
CITAB / RD (7505P)

*[Handwritten signature]*

THROUGH: Shyam Mathur, Ph.D.  
Product Chemistry Team Leader  
CITAB /RD (7505P)

*[Handwritten signature and date: 03-02-16]*

TO: Shanta Adeeb / Kathryn Montague PM 23  
Herbicide Branch / Registration Division (7505P)

REGISTRANT: Rotam Limited

**INTRODUCTION:**

Rotam Limited is amending the CSFs to address the analysis of impurities of toxicological concern. The basic CSF currently on file did not list these impurities and was eliminated and replaced by the Alternate CSF #1 currently on file as shown in the table below:

CSF Formulation	Date of CSF	Source of Technical	Revision
Basic	9/6/2011		This source is eliminated.
Alternate #1	12/04/2014		Changed to "Basic" formulation with CSF date of 1/25/2016.
Alternate #2	11/15/2014		Changed to "Alternate #1" with CSF date of 1/25/2016.
Alternate #3	1/19/2015		Changed to "Alternate #2" with CSF date of 1/25/2016.



**DP BARCODE: 425680; DECISION NO.: 399330; Reg. No. No.:81598-12**

**PRODUCT NAME: Rotam Dicamba Technical: PC CODE(s): 029801;**

#### **SUMMARY OF FINDINGS:**

There are no additional data to review but the “new” basic and alternate CSFs 1 and 2 all dated January 25, 2016 have been previously approved and have been supported by CITAB reviews of data that included five batch analysis for each manufacturing site. Impurities of significant toxicological concern were adequately analyzed and listed on the CSFs all dated January 25, 2016. Analytical data indicated that the impurities of significant toxicological concern (Polychlorinated Dibenzo-dioxins and polychlorinated Dibenzofurans) were below the level of concern.

The revised CSFs are supported by CITAB (previously TRB) reviews and MRIDs as listed in the following table:

<b>CSF</b>	<b>Date</b>	<b>Manufacturing Site</b>	<b>CITAB review DP/Date</b>	<b>MRID</b>
<b>Basic</b>	<b>1/25/16</b>		<b>424509 (see data in Confidential Appendix)</b>	<b>492264-01 to -03</b>
<b>Alternate #1</b>	<b>1/25/16</b>		<b>424886 04/23/15</b>	<b>495142-01 to -03</b>
<b>Alternate #2</b>	<b>1/25/16</b>		<b>425680 07/13/15</b>	<b>495495-01 to -04</b>

#### **CONCLUSIONS:**

The CITAB has reviewed the revised CSFs and the product chemistry data submitted to support the basic and alternate CSF #1 and 2 for “Rotam Dicamba Technical” and has concluded that:

1. The data previously submitted and reviewed for guidelines 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) and all relevant production data provided for the production sites are acceptable.
2. Analysis was conducted in comparison to levels of spiked samples (see Confidential Appendix for levels of quantifications). Chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans impurities which are of toxicological concern were below levels of quantification and concern.
3. The basic and alternate CSFs #1 and 2 all dated January 25, 2016 are acceptable. The lower and upper certified limits for the A.I. are within EPA’s Standard Certified Limits set on the basic CSF.

